UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/511,972	02/24/2000	Boris Skurkovich	011-2 (53663-5004)	6154

7590 04/18/2003

Morgan, Lewis & Bockius
1701 Market ST.
Philadelphia, PA 19103

EXAMINER
MERTZ, PREMA MARIA

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 04/18/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/511,972	Skurkovich et al.
Examiner	**Art Unit**
Prema Mertz	1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Oct 10, 2002*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-99* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-99* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-3, 10, 14, 20, 27, 32-36, 49-50, 57-59, 68-69, 76-77, 84-85, are drawn to an allergy vaccine comprising IgE and a method for preventing an allergic response by administering the vaccine, classified in Class 424, subclass 130.1.

Group 2. Claims 1-3, 10, 14, 20, 27, 32-36, 49-50, 57-59, 68-69, 76-77, 84-85, are drawn to an allergy vaccine comprising an IgE receptor and a method for preventing an allergic response by administering the vaccine, classified in Class 514, subclass 2.

Group 3. Claims 1-3, 4-6, 10, 12-13, 20-23, 27, 32-34, 49-50, 57-59, 68-69, 76-77, 84-85, are drawn to an allergy vaccine comprising IL-3 and a method for preventing an allergic response by administering the vaccine, classified in Class 424, subclass 85.2.

Group 4. Claims 1-3, 4-9, 10, 12-13, 20-27, 32-34, 49-50, 57-59, 68-69, 76-77, 84-85, are drawn to an allergy vaccine comprising IL-4 and a method for preventing an allergic response by administering the vaccine, classified in Class 424, subclass 85.2.

Group 5. Claims 1-3, 4-8, 10, 12-13, 20-25, 27, 32-34, 49-50, 57-59, 68-69, 76-77, 84-85, are drawn to an allergy vaccine comprising IL-5 and a method for preventing an allergic response by administering the vaccine, classified in Class 424, subclass 85.2.

Group 6. Claims 1-3, 4-5, 10, 12-13, 20-22, 27, 32-34, 49-50, 57-59, 68-69, 76-77, 84-85, are drawn to an allergy vaccine comprising IL-6 and a method for preventing an allergic response by administering the vaccine, classified in Class 424, subclass 85.2.

Group 7. Claims 1-3, 4, 10, 12-13, 20-21, 27, 32-34, 49-50, 57-59, 68-69, 76-77, 84-85, are drawn to an allergy vaccine comprising IL-10 and a method for preventing an allergic response by administering the vaccine, classified in Class 424, subclass 85.2.

Group 8. Claims 1-7, 10, 12-13, 20-24, 27, 32-34, 49-50, 57-59, 68-69, 76-77, 84-85, are drawn to an allergy vaccine comprising IL-13 and a method for preventing an allergic response by administering the vaccine, classified in Class 424, subclass 85.2.

Group 9. Claims 1-3, 4-6, 10, 11-13, 20-23, 27, 49-50, 57-59, 76-77, 84-85, are drawn to an allergy vaccine comprising IL-3 receptor and a method for preventing an allergic response by administering the vaccine, classified in Class 514, subclass 2.

Group 10. Claims 1-3, 4-9, 10, 11-13, 20-27, 49-50, 57-59, 76-77, 84-85, are drawn to an allergy vaccine comprising IL-4 receptor and a method for preventing an allergic response by administering the vaccine, classified in Class 514, subclass 2.

Group 11. Claims 1-3, 4-8, 10, 11-13, 20-25, 27, 49-50, 57-59, 76-77, 84-85, are drawn to an allergy vaccine comprising IL-5 receptor and a method for preventing an allergic response by administering the vaccine, classified in Class 514, subclass 2.

Group 12. Claims 1-3, 4-5, 10, 11-13, 20-22, 27, 49-50, 57-59, 76-77, 84-85, are drawn to an allergy vaccine comprising IL-6 receptor and a method for preventing an allergic response by administering the vaccine, classified in Class 514, subclass 2.

Group 13. Claims 1-3, 4, 10, 11-13, 20-21, 27, 49-50, 57-59, 76-77, 84-85, are drawn to an allergy vaccine comprising IL-10 receptor and a method for preventing an allergic response by administering the vaccine, classified in Class 514, subclass 2.

Group 14. Claims 1-7, 10, 11-13, 20-24, 27, 49-50, 57-59, 76-77, 84-85, are drawn to an allergy vaccine comprising IL-13 receptor and a method for preventing an allergic response by administering the vaccine, classified in Class 514, subclass 2.

Groups 15-20.Claims 14-15, 20, 27, 35-36, 49-50, 76-77, 84-85, are drawn to an allergy vaccine comprising one of IFN-α, IFN-α receptor, histamine, histamine receptor, leukotriene or leukotriene receptor, respectively, and a method for preventing an allergic response by administering the vaccine, classified in Class 424, subclass 85.7.

Groups 21-30.Claims 16-19, 28-31, 51-52, 70-71, 60-61, 78-79, 86-87, are drawn to an allergy vaccine comprising a nucleic acid encoding a protein selected from one of IgE, IgE receptor, interleukin, interleukin receptor, IFN-α, IFN-α receptor, histamine, histamine receptor, leukotriene or leukotriene receptor, respectively, and a method for preventing an allergic response by administering the vaccine, classified in Class 514, subclass 44.

Groups 31-36. Claims 37-40, 41-45, 53-54, 62-64, 80-81, 90-94, are drawn to a method for preventing an allergic response by administering a vaccine comprising a soluble interleukin

receptor and an antibody to an interleukin receptor wherein the IL is one of IL-3, IL-4, IL-5, IL-6, IL-10, or IL-13, respectively, classified in Class 514, subclass 2.

Groups 37-48.Claims 41-42, 53-54, 62-64, 72-73, 80-81, 88-89, are drawn to a method for treating an allergic response by administering a vaccine comprising one of the following, anti-IgE antibody, anti-IgE receptor antibody, a soluble IgE receptor, anti- interleukin antibody, anti-interleukin receptor antibody, anti-IFN-α antibody, anti-IFN-α receptor antibody, anti-histamine antibody, anti-histamine receptor antibody, anti-leukotriene antibody, anti-leukotriene receptor antibody or soluble leukotriene receptor antibody respectively, classified in Class 424, subclass 130.1.

Groups 49-62.Claims 46-48, 55-56, 65-67, 74-75, 82-83, are drawn to a method for treating an allergic response by administering at least one of the following antisense nucleic acid complementary to a nucleic acid encoding a protein selected from the group consisting of IgE, IgE receptor, IL-3, IL-4, IL-5, IL-6, IL-10, IL-13, IL-3 receptor, IL-4 receptor, IL-5 receptor, IL-6 receptor, IL-10 receptor, IL-13 receptor, classified in Class 514, subclass 44.

Groups 63-68.Claims 65-67, are drawn to a method for treating an allergic response by administering at least one of the following antisense nucleic acid complementary to a nucleic acid encoding a protein selected from the group consisting of IFN-α, IFN-α receptor, histamine, histamine receptor, leukotriene or leukotriene receptor, respectively, classified in Class 514, subclass 44.

Should any one of the Groups from 1-68 be elected, Applicant is required to select one polypeptide, one antibody or one nucleic acid to be administered. For example, an Il-3 polypeptide is considered, absent factual data to the contrary, a distinct polypeptide. Once one polypeptide, one antibody or one nucleic acid to be administered is selected, all other polypeptides, antibodies and nucleic acids to be administered will be withdrawn from consideration.

The inventions are distinct, each from the other because of the following reasons:

Inventions 1-68 are independent and distinct, each from the other, because the methods are practiced with materially different products which are structurally and chemically different, the novelty of the inventions lying in the products being administered and not the processes. The only feature in common in the instant inventions is "a method of treating or preventing an allergy", which does not constitute the special technical feature lacking from the prior art because this method can be used with a composition other than the instant products such as anti-histamine analogues. Distinctness is further shown because each of these products in each method can be made and used without any one or more of the other products. The products in the different Groups are physically, chemically and biologically distinct from each other, and if patentable would support separate patents. Furthermore, separate search terms would be required for searching the literature, eg. a search of the literature for an association of IL-6 with allergy would not necessarily reveal art for an association of IL-3 receptor, IFN-α, or leukotrienes with allergy. Similarly, a search of the literature with an antisense nucleic acid complementary to a nucleic acid

encoding IgE would not necessarily reveal art for an association of leukotrienes, IFN-α or histamine receptor with allergy.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their recognized divergent subject matter as defined by MPEP... § 808.02, the Examiner has *prima facie* shown a serious burden of search (see MPEP.. § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 305-3014 or (703 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 746-5300.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Prema Mertz

Prema Mertz Ph.D.
Primary Examiner
Art Unit 1646
March 26, 2003